

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applica	ation of:)	
	Zatezalo et al.))	
)	Art Unit: 3737
Serial No.:	10/309,413)	
	·)	Examiner: Ramirez, John
Filed:	December 3, 2002)	Fernando
	,)	
For:	Programmable Injector Control)	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.56 AND NOTICE OF RELATED LITIGATION UNDER 37 CFR 1.178

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement and Notice of Related Litigation are filed in accordance with 37 CFR §1.56, §1.97, §1.98 and §1.178. Applicants herewith disclose references and call to the attention of the Examiner the pending federal court litigations relating to U.S. Patent No. 6,339,718 ("the '718 patent") and U.S. Patent No. 6,643,537 ("the '537 patent"), the patents to which this application claims priority, that may be deemed to be relevant to the patentability of the above-identified application.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 6, 2005.

Villiam L. Warren – Reg. No. 36,714

Serial No.: 10/309,413

Filing Date: December 3, 2002 IDS & Notice of Litigation

Applicants respectfully submit that the references and any litigation related documents and/or materials are made of record to assist the Examiner in the examination of the above-identified The Examiner is respectfully requested to fully consider the items and to application. independently ascertain their teachings and relevance to this application.

I. References Cited in Corresponding Applications

The references cited in the attached Forms 1449 have been disclosed and/or made of record in related pending Application Serial No. 09/941,224, and copies thereof may be found in the corresponding application file.

- II. Notice of Pending Litigations Related to the '718 and the '537 patents: MPEP 2001.06 (c)
- 1. Medrad, Inc. v. Tyco Healthcare Group, LP, et al., Civil Case No. 01-1997-DEC, U.S.D.C. (W.D. Penn.) ("the Pennsylvania litigation")

The litigation documents exchanged by the parties of this Pennsylvania litigation were listed on the Form PTO-1449 and previously submitted to the Examiner on September 2, 2003. In addition, on August 11, 2003, Medrad executed a Covenant indicating that the parties are desirous of dismissing the portions of the Pennsylvania litigation relating to the '718 patent. The Covenant stated that Medrad did "not to sue and forever release" Tyco et al. from any and all claims "solely relating to infringement of ... the '718 patent based on the manufacturing, use, sale and/or offer for sale of Optistar MR Injector Systems that are or have been publicly available for purchase in the United States as of the date hereof." A citation of the Covenant listed on the attached Form PTO-1449 has been disclosed and/or made of record in the related pending Application Serial No. 09/941,224, and a copy thereof may be found in the corresponding application file.

Tyco Healthcare Group LP, et al. v. Medrad, Inc., Civil Case No. 04-773, U.S.D.C. (S.D. Ohio) ("the Ohio litigation")

Applicants hereby notify the Examiner that the '718 patent and the '537 patent' have also been involved in the Ohio litigation instituted by Tyco Healthcare Group LP ("Tyco"), Mallinckrodt Inc. ("Mallinckrodt") and Liebel-Flarsheim Company ("L-F"), against Medrad for

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Declaratory Judgment. This Ohio litigation was filed in the United States District Court for the Southern District of Ohio on November 15, 2004, under Civil Case No. 04-773.

In the Ohio litigation, Tyco et al. alleged that the '718 and the '537 patents are invalid, unenforceable and the claims of the '718 and the '537 patents are not infringed (*See* Tyco et al.'s Complaint of November 15, 2004). The litigation documents cited in the attached Forms 1449 have been disclosed and/or made of record in the related pending Application Serial No. 09/941,224, and copies thereof may be found in the corresponding application file.

- 1) Tyco et al.'s Complaint for Declaratory Judgment and Jury Demand dated November 15, 2004;
 - 2) Medrad's Answer and Counterclaims filed December 28, 2004;
 - 3) Tyco's Reply to Defendant's Counterclaims filed January 20, 2005;
 - 4) Tyco's First Set of Interrogatories Nos. 1-8 to Defendant filed February 7, 2005;
- 5) Tyco's First Set of Requests for Production of Documents to Defendant filed February 7, 2005;
- 6) Medrad's Responses and objections to Plaintiffs' First Set of Requests for Production of Documents to Defendant filed March 11, 2005;
- 7) Medrad's Responses to Plaintiffs' First Set of Interrogatories Nos. 1-8 to Defendant filed March 11, 2005;
- 8) Medrad's First Set of Requests for Production of Documents and Things to Plaintiffs filed March 18, 2005;
- 9) Medrad's First Request for Entry Upon Land and Inspection of Things Thereon to Plaintiffs filed March 18, 2005;
- 10) Medrad's Consent Motion to Amend Answer and Counterclaims filed March 24, 2005;
 - 11) Medrad's Amended Answer and Counterclaims filed March 24, 2005;
 - 12) Medrad's First Set of Interrogatories (Nos. 1-9) filed March 24, 2005;

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- 13) Tyco's Reply to Defendant's Amended Counterclaims filed April 27, 2005;
- 14) Tyco's Response to Medrad's First Set of Requests for Production of Documents and Things filed May 20, 2005; and
- 15) Tyco's Response to Medrad's First Set of Interrogatories (Nos. 1-9) field May 26, 2005.

In Medrad's Answer and Counterclaims to Tyco's Complaint, and later, in Medrad's Amended Answer and Counterclaims to Tyco's Complaint, Medrad modified the "Facts" section of its Counterclaims by referring to U.S. Patent No. 6,743,205 ("the '205 patent), adding a Third Counterclaims alleging infringement of the '205 patent, and modifying Medrad's Prayer for Relief. Validity and infringement allegations relating to the '718 and the '537 patents are also set forth in the Amended Answer and the First and Second Counterclaims. However, in Tyco's Reply to Medrad's Counterclaims and Amended Counterclaims, Tyco et al. denied the infringement allegations of Medrad's Counterclaims relating to the '718 patent and the '537 patent, respectively.

In Medrad's Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-8), Medrad objected that the interrogatory was premature in that limited discovery has been done. Medrad further asserted that Medrad's investigation of infringement by Tyco et al. is ongoing but alleged that Plaintiffs' OptiVantageTM DH injection system literally infringes at least claims 24 and 27 in the '718 patent (pages 7-8) and claims 6, 19 and 22 in the '537 patent (pages 4-7). In Medrad's Responses and Objections to Plaintiffs' First Set of Requests for Production of Documents and Things, Medrad objected to each request as being duplicative, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence (General Objections on page 1; and Responses to each Request).

In Tyco's Responses to Medrad's First Set of Requests for Production of Documents and Things, Tyco simply objected each Request to the extent that 1) each Request sought the production of documents or things that are protected by the attorney-client and/or work product privileges; 2) the Requests sought information unrelated to any claim or defense in this action and is likely to lead to the discovery of admissible evidence; and/or 3) the Requests were overly

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broad and burdensome. In Plaintiffs' Responses to Medrad's First Set of Interrogatories (Nos. 1-9), non-infringement allegations relating to the '718 patent and the '537 patent are set forth on page 6 (Response to Interrogatory No. 5) with references to the preliminary non-infringement chart attached as Exhibit A. Unpatentability and invalidity allegations, and unenforceability due to inequitable conduct allegations relating to the '718 patent and the '537 patent are set forth on pages 6-8 (Response to Interrogatory No. 6); pages 8-9 (Response to Interrogatory No. 7); and pages 9-21 (Response to Interrogatory No. 8). Note that information relating to the '718 patent and the '537 patent of alleged prior art, Nemoto Sonic Shot 50 MR injector, the Medrad MR Spectris Injector, the Injektron 82 MRT 1.4 manual, U.S. Patent No. 5,472,403 to Cornacchia, and U.S. Patent No. 5,806,519 to Evans, III were disclosed in numerous documents submitted with the Information Disclosure Statement, and were also considered by the Patent Office during the prosecutions of the '718 patent and the '537 patent, respective (See, for example, IDS submitted on November 1, 2000; First Office Action dated December 18, 2000; and IDS submitted on May 17, 2001 during the prosecution of the '718 patent; see also, for example, IDS and Notice of Related Litigation submitted on May 19, 2003, and IDS submitted on May 29, 2003 during the prosecution of the '537 patent).

Applicants believe that certain of the alleged prior art references are not or may not be prior art to the application, and therefore reserve the right to assert that one or more of the references is not prior art to this application. Moreover, Applicants believe they can successfully swear behind many, if not all, of the Section 102 (a) and (e) references based on prior conception and/or reduction to practice.

Nevertheless, Applicants would like the Examiner to at least initially consider the subject matter disclosed in the relevant references vis-à-vis the pending claims because Applicants believe the claims will define over the references.

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The Examiner is encouraged to call the undersigned attorney at 404-853-8081 if doing so will facilitate prosecution of the application. No fees are believed to be due at this time. However, the commissioner is hereby authorized to charge any additional fees due or credit any overpayment to Deposit Account 19-5029 (Ref. 23578-0008).

Respectfully submitted,

William L. Warren Reg. No. 36,714

SUTHERLAND ASBILL & BRENNAN LLP

999 Peachtree Street, NE Atlanta, Georgia 30309-3996

Phone: 404.853.8000 Fax: 404.853.8806

Attorney Docket No.: 23578-0008

PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE			SURF	Filing Date	December 3, 2002		
				First Named Inventor	Zatezalo et al.		
STATEMENT BY APPLICANT (Use as many sheets as necessary)				Art Unit	3737		
			ary)	Examiner Name	Ramirez, John Fernando		
Sheet	1	of	2	Attorney Docket Number	23578.0008		

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	U. S. PATENT DOCUMENTS					
Examiner Cite No.1		Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant	
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Signature	Considered	

"EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. To Japanese patent document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Application Number	10/309,413			
Filing Date	December 3, 2002			
First Named Inventor	Zatezalo et al.			
Art Unit	3737			
Examiner Name	Remirez, John Fernando			
Attorney Docket Number	23578.0008			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the articles (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	C1	E-Z-EM, Inc.; PercuPump II Touch*Screen CT Injector System; Manual and Operations Guide; 1996	
	C2	Liebel-Flarsheim Company CT 9000 Digital Injection System Operator's Manual; 800850 Rev F; Nov. 1995	
	C3	Covenant, Civil Case No. 01-1997-DEZ, Medrad, Inc. v. Tyco Healthcare Group LP, et al. (August 11, 2003)	T
· · · · · · · · · · · · · · · · · · ·	C4	Tyco's Complaint for Declaratory Judgment and Jury Demand, Civil Case No. 04-773, Tyco Healthcare Group LP et al. v. Medrad, Inc. (November 15, 2004)	
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	C18	Tyco's Response to Medrad's First Set of Interrogatories (Nos. 1-9), Civil Action No. 04-773, Tyco Healthcare Group LP et al. v. Medrad, Inc. (May 26, 2005).	ļ
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with

next communication to applicant.

Applicant's unique citation designation number (optional).
Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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